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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,855	06/22/2001	Dirk M. Anderson	2883-US	8635

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,855	ANDERSON, DIRK M.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-33* is/are pending in the application.

4a) Of the above claim(s) *22 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21,23-28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Applicants' Response to Restriction Requirement, dated October 3, 2003, filed on November 6, 2003 is acknowledged. Claims 1-13 have been canceled. New claims 14-33 have been added. New claims further require a restriction because the method is *in vivo* in claims 22 and 29 and distinct from the other method claims. Examiner called the Attorney and it was agreed upon that claims 22 and 29 would be withdrawn from the prosecution. Therefore, claims 14-21, 23-28 and 30-33 are currently pending and are under examination.

Priority

Applicant's claim for priority is acknowledged. This application is a continuation of US application PCT/US99/30523, filed on December 22, 1999, which claims the benefit under 35 U.S.C. 119 (e) of provisional application US 60/113820 filed December 23, 1998. The provisional application fails to provide the sequence of SEQ ID NO: 5 therefore the priority date December 22, 1999 would be considered for the priority date, which is the filing date of PCT/US99/30523 application.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-21, 23, 24-28, 30-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting binding between a ss3939 polypeptide and a binding partner of said ss3939 polypeptide, does not reasonably provide enablement for all the soluble proteins, and fragments or mutants generated from any position located on the sequence of the ss3939 protein. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The method provides a soluble protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 5 (amino acids 22 through 227 of SEQ ID NO: 2); amino acids 24 through 227 of SEQ ID NO: 2; amino acids 25 through 227 of SEQ ID NO: 2 wherein the binding partner of said ss3939 polypeptide is expressed by human umbilical vein endothelial cells (claim 14, 24), wherein the ss3939 polypeptide is expressed by a dendritic cell (claim 15, 25), wherein the binding partner of the ss3939 polypeptide comprises one or more polysaccharide moieties (claim 16, 26); comprises the amino acid sequence of SEQ ID NO: 5 (claim17); wherein the soluble polypeptide is an oligomer (claim18, 27); a dimer (claim 19); wherein the soluble polypeptide comprises an Fc polypeptide (claim 20, 28); comprises a leucine zipper (claim 21); wherein the method comprises providing the polypeptide *in vitro* (claim 23).

Claims 30-33 drawn to a method that provides a soluble protein comprising an amino acid sequence that is at least 90% identical to SEQ ID NO: 5, wherein the binding partner of said ss3939 polypeptide is expressed by human umbilical vein endothelial cells, and wherein the soluble polypeptide binds to human umbilical vein endothelial cells; wherein the soluble polypeptide is at least 95% identical to SEQ ID NO: 5; wherein the soluble polypeptide has from one to ten deletions, insertions, or substitution of amino acid residues when compared to SEQ ID NO: 5

The specification, however, only discloses cursory conclusions (see page 13, 17), without data to support the findings. See the discussion below.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include: 1) the nature of the invention; 2) the breadth of the claims; 3) the predictability or unpredictability of the art; 4) the amount of direction or guidance presented; 5) the presence or absence of working examples; 6) the quantity of experimentation necessary; 7) the state of the prior art; and, 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The nature of the invention:

The nature of the invention is defined by the claims, which include method for inhibiting binding between an ss3939 polypeptide and a binding partner of said ss3939 polypeptide. The method provides a soluble protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 5 (amino acids 22 through 227 of SEQ ID NO: 2); amino acids 24 through 227 of SEQ ID NO: 2; amino acids 25 through 227 of SEQ ID NO: 2, or fragments or mutants thereof; wherein the binding partner of said ss3939 polypeptide is expressed by human umbilical vein endothelial cells. However specification does not provide the information on the structure and function of the claimed fragments and mutants. The nature of the variation makes it entirely unpredictable what might be considered a variant before the isolation of such a sequence has actually taken place. For example, pages 13 -19 of the specification do not provide chemical, physical, and biological characteristics or function of fragments or mutants.

The breadth of the claims:

The breadth of the claims encompasses unspecified number of variants regarding the soluble polypeptide and the binding partner of said polypeptide, which are not specifically described or demonstrated in the specification. Given the lack of teachings or guidance in applicants' disclosure regarding the variants of soluble protein other than the one specifically referenced Fc fusion protein, such as ss3939/Fc described in Examples 2 and 5, comprising the N-terminus of a soluble ss3939 polypeptide fused to an Fc C-terminal domain it would require undue experimentation by one skill in the art to make mutants/fragments of ss3939 polypeptide or other undefined molecules having an activity substantially equivalent to that of ss3939 polypeptide, commensurate in scope with the claims. The specification indicates the general methods of generating mutants of the soluble protein ss3939 claimed at page 17-18. The specification fails to provide the positions in the sequence, which are critical to the protein's structure/function relationship, such as sites or regions directly involved in binding and activity.

The amount of direction or guidance presented;

The presence or absence of working examples; and

The quantity of experimentation necessary:

Given the breadth of the claims in the invention, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to make and use the mutants/fragments/variants of broadly claimed group of ss3939 proteins. Such teachings are absent in the specification. The specification has disclosed a method for inhibiting binding between ss3939 polypeptide and a binding partner of said ss3939 and variants thereof, wherein the binding partner is expressed by human umbilical vein endothelial cells. There is no guidance as to how the functional fragments and mutants of the claimed ss3939 protein can be generated. The specification has provided no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein, which are tolerant to change (e.g. by amino acid deletions, insertions or substitutions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active protein variants, this is not adequate guidance as to the nature of active derivatives that may be constructed. The working examples are exclusively drawn to making one fusion protein comprising the extracellular domain of ss3939 (amino acids 22-227 of SEQ ID NO: 2), and a c-terminal Fc domain (Example 2), and that is used to test the ability of ss3939 to bind to host cells expressing cognate binding partner, such as polysaccharide moieties (Example 5).

In consideration of each of factors, it is apparent that undue experimentation is necessary because in summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the guidance/the teaching in the specification is limited, and the outcome is unpredictable for the various modified forms. It is necessary to have additional guidance to carry out further experimentation to assess the property of the variants. Therefore, due to large quantity of experimentation necessary to generate the infinite number of variants and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required to in order to provide activity, the absence of working examples directed to

same, the complex nature of the invention and the breadth of the claims, which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 16, 26, 30, 31, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 26 are indefinite because of the phrase "one or more." It is not clear how many polysaccharide moieties are there in the binding partner of ss3939.

Claims 30 and 31 are indefinite as to the biological activity, sequence and physical characteristics of the fragments.

Claims 32 and 33 are indefinite as to the biological activity, size, sequence and physical characteristics of the mutants. Claims 32 and 33 are also indefinite because it is not clear how many amino acid residues are deleted, inserted or substituted in relation to the sequence of SEQ ID NO: 5.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16, 20, 26, 28, 30, 31 and 32 are rejected under 35 USC 102 (a) as being anticipated by Wood et al. (WO 99/14328, March 25, 1999, IDS Ref No B1). Wood et al. teach secreted and transmembrane polypeptides (see abstract). The reference teaches a cDNA clone that encodes a novel lectin polypeptide molecule, designated as "PRO234", having amino acid residues 1-382 of Fig 50 (SEQ ID NO: 137), see pages 19, 42, 57, 75, 131, 132. The PRO234 has 98.7% sequence identity to amino acids 22-227 of SEQ ID NO: 2 (see sequence alignment result, Chen et al. "Amino acid sequence of protein PRO234, Database: A_Geneseq_19June03, Accession NO: AAY13367, June 25, 1999). This reads on claims 30 and 31 of instant application where soluble polypeptide has 90% (claim 30) and 95% (claim 31) sequence identity to amino acids 22-227 of SEQ ID NO: 2. Further the PRO234 sequence alignment also indicates 8 amino acid residues substitution when compared to SEQ ID NO: 5 (amino acids 22-227 of SEQ ID NO: 2), anticipating claim 32 where polypeptide has one to ten deletions, insertions or substitutions of amino acid residues. Wood et al. also teach that oligosaccharides are well positioned to act as recognition novel lectins due to their cell surface location and structural diversity (pages 19-20), therefore, PRO234 is considered for the binding partner of the ss3939 polypeptide comprising one or more polysaccharides moieties (claims 16, 26). Wood et al. also teach a fusion protein comprising the "PRO" protein fused to heterologous polypeptide sequences. This fusion protein is considered for the fusion protein of soluble polypeptide comprising an Fc polypeptide (claims 20, 28)

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 10:00 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
January 9, 2004

ROBERT A. WAX
PRIMARY EXAMINER